Cost-effectiveness of posterior cervical foraminotomy(FOR) versus anterior cervical discotomy with fusion (ACDF) for cervical soft/osteophytic disc disease. A randomized controlled multicenter study. FACET study (Foraminotomy Acdf Cost-Effectiveness Trial)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47024

Source
ToetsingOnline

Brief title
FACET study

Condition

- Head and neck therapeutic procedures

Synonym
cervical radicular syndrome (CRS), cervicobrachialgia.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cervical Radiculopathy, Cost-effectiveness, Multicentre, Randomized

Outcome measures

Primary outcome

Reduction of cervical radicular pain measured by the ODOM criteria (4 point

Likert scale) and VAS arm pain.

Secondary outcome

The secondary outcomes include Work Ability (Work Ability Index, single item),

Quality of Life (Euroqol-5D), Neck Pain (VAS), Neck disability index(NDI),

Complications and Productivity related costs(iPCQ) and medical costs(IMCQ).

Study description

Background summary

The majority of scientific data on discogenic or spondylotic foraminal stenosis are lacking comparative data. Within this era, well-validated outcome instruments are mandatory and there is a need for comparative data to develop evidence based treatment recommendations. At this time, there are no evidence-based guidelines on the most appropriate surgical treatment strategy for cervical discogenic or spondylotic stenosis of the cervical neuroforamen. The results of this study will provide surgical treatment recommendations for patients with discogenic or spondylotic cervical foraminal stenosis and contribute to the understanding of its short- and long-term clinical postoperative course.

Study objective

The study objectives are to compare the clinical outcome(decrease of radiculopathy), complications rates and cost-effectiveness of FOR to ACDF within the group of patients with a CRS due to soft disc compression or osteophyte compression of a cervical root. Work absenteeism of this specific study group will also be studied.

Hypothesis:
H0: The null hypothesis is that the percentage for those on the ACDF treatment is better than the percentage for those on the
FOR treatment by an amount of 10%.
H1: Reject the null hypothesis. FOR is no worse than ACDF by a delta of 10%.
In this multicenter non inferiority trial we want to reject the H0 and
accept H1.

Patients with a monosegmental cervical radiculopathy due to a lateral/foraminal stenosis (discogenic or osteophytic
component) operated with the FOR technique will have no worse outome on the primary endpoint(decrease of radiculopathy),
lower surgical and hospital costs, lower morbidity and lower work absenteeism in respect to the patients operated with the
ACDF technique.

The study objectives are:
1.compare the clinical outcome(decrease of radiculopathy) of FOR to ACDF within the group of patients with a CRS due to soft
disc compression or osteophyte compression of a cervical root.
2.compare complication rates of both FOR to ACDF,
3.compare cost-effectiveness of FOR to ACDF,
4.Investigate work absenteeism.

Study design

This study is a nationwide, prospective, multicenter, researcher blinded, randomized controlled trial with a follow up period of 24 months.

Intervention

ACDF technique:
Microsurgical discectomy was performed through a ventral approach described by Smith and Robinson (1958). Procedure can be executed with microscope or loup magnification. Exploration of the intervertebral disc and removal of bony spurs with a high-speed drill. Subsequently removal of the posterior part of the intervertebral space. The posterior ligament is dissected and removed with rongeurs. Subligamentous discal fragments are removed. The proximal part of the neuroforamen is inspected for discal remnants. If an osteophytic component is present, the uncovertebral joint is reduced to remove the osteophytic

component. An intervertebral spacer is placed to keep height of the intervertebral disc space. No additional plate fixation is used.

FOR technique: All patients are operated in prone position with the head fixated in a 3-point head holder. After determining the correct level on lateral radiograph, a vertical 4 cm midline incision is made, and the lateral lamina/medial facet joints are exposed. A retractor is placed adequately. Under the operating microscope or loup magnification and after a second confirmation of the correct level, a partial hemilaminectomy and foraminotomy with partial facetectomy of the involved level is performed with high-speed drills. The percent of the facet resection was based on the extent of the foraminal pathology. In cases of pure soft discs, the proximal root is visualized adequately for removal of the compressing disc material. In cases of foraminal stenosis, bony decompression and skeletonization of the proximal root were performed carefully using a 4-mm diamond burr, small rongeurs, and dissectors.

Study burden and risks

Patients are treated within the concept of *care as usual*. Both operative techniques are part of the neurosurgeons basic skills and training. Both operative techniques are index techniques to operate on cervical discal herniations. Differences between risks and clinical outcome between both procedures are unknown and are objective of this study. The burden for patients participating in this trial is low (see table *Visit plan*). Patients are asked to fill out questionnaires after 6, 24, 52, 78 and 104 weeks. Time to fill out the questionnaire is approximately 30 minutes per follow up moment. There are no benefits compared to care as usual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patient has sufficient mastery of the Dutch language to fill out the questionnaires.
- Age between 18 and 80 years.
- Cervical foraminal stenosis causing monoradiculopathy of C4, C5, C6, or C7 and requiring decompression of 1neuroforamen. Foraminal stenosis due to a soft disc component is defined as: 2/3 of the total discal component is located intraforaminally and a maximum of 1/3 of the total discogenic component is located medially, within the spinal canal. Radiculopathy is defined as pain, paralysis or paresthesia in corresponding nerve root distribution areas of C4, C5, C6,or C7,and must include at least arm or shoulder pain with minimum of 30 mm on a 100 mm visual analog scale.
- No response to conservative treatment for eight weeks or presence of progressive symptoms or signs of nerve root compression in the face of conservative treatment.
- Soft disc/Spondylitic foraminal stenosis (determined by MRI and CT and/or right or left oblique X-ray of the cervical spine) at the treatment level correlating to primary symptoms.
- Psychosocially, mentally, and physically able to fully comply with this protocol, including adhering to scheduled visits, treatment plan, completing forms, and other study procedures.
- Signed and dated informed consent document prior to any study-related procedures.

Exclusion criteria

- Multisegmental CRS.
- Median located disc protrusion or osteophytic protrusion.
- Foraminal compression of C8.
- Spinal cord compression with clinical myelopathy.
- Radiological myelopathy.
- History of cervical spine surgery.
- Obesity WHO class II or higher (BMI >= 35).
- Osteoporosis / chronic use of corticosteroïds.

- ASA 4 and 5 patients.
- Incapability to speak and write the Dutch language
- Pregnancy
- Active malignancy
- Abundant use of alcohol, drugs, narcotics and recreational drugs.
- Contra-indications for anesthesia or surgery
- Patient has used another investigational drug or device within the 30 days prior to surgery

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2016
Enrollment:	308
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-12-2015
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-12-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24269
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54380.042.15
OMON	NL-OMON24269